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Sheet 1

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known				
Application Number	10/802,273			
Filing Date	03/17/04			
First Named Inventor	Rodriguez			
Art Unit	1614			
Examiner Name	Leslie A. Royds			
Attorney Docket Number	31162B	7		

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
LAR		<sup>US-</sup> 3,957,982	05-18-1976	Lachnit-Fixson et al.	
WALL		<sup>US-</sup> 3,969,502	07-13-1976	Lachnit-Fixson	
DAR		<sup>US-</sup> 4,390,531	06-28-1983	Edgren	· · · · · · · · · · · · · · · · · · ·
LAST		<sup>US-</sup> 4,530,839	07-23-1985	Pasquale	
NAGL		<sup>US-</sup> 4,544,554	10-01-1985	Pasquale	
M		<sup>US-</sup> 4,616,006	10-07-1986	Pasquale	
1002		<sup>US-</sup> 4,621,079	11-04-1986	Lachnit-Fixson et al.	
TAL		<sup>US-</sup> 4,628,051	12-09-1986	Pasquale	
HAL		<sup>US-</sup> 4,760,053	07-26-1988	Labrie	
IAL		<sup>US-</sup> 4,817,819	04-04-1989	Kelly	
NAV		<sup>US-</sup> 4,833,125	05-23-1989	Neer	
HALL		<sup>US-</sup> 4,855,305	08-08-1989	Cohen	
LAR		<sup>US-</sup> 4,906,169	03-06-1990	Chien	
LAR		<sup>US-</sup> 4,921,843	05-01-1990	Pasquale	
NAG		us- 4,962,098	10-09-1990	Boissonneault	
HAR		<sup>US-</sup> 5,108,995	04-28-1992	Casper	
LAR		<sup>US-</sup> 5,256,421	10-26-1993	Casper	
LAR		<sup>US-</sup> 5,262,408	11-16-1993	Bergink	
1902		US- 5,280,023	01-18-1994	Ehrlich et al.	

Examiner Initials*	Cite No.1	FORE Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> Number <sup>4</sup> 'Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	Ľ
LAAR		EP 0 253 607 A1	01-20-1988	Upton	-	
		EP 0 253 607 B1	01-20-1988	Upton	·	
MAC		EP 0 628 312 B1	12-14-1994	Wablat		Г
NAME		WO 95/26730 A1	10-12-1995	Schering		
JAN-		WO 97/11680	04-03-1997	Elliesen		Г
NA		MO 98/10771 A1 M	03-19-1998	Rodriguez		Г

Examiner Signature Date Considered 11 OCTOBER 2006

\*EXAMINER: Initial of perence considered, whether of not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include appy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). 'See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document ender WIPO Standard ST.16 if possible. 'Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form	1449/PTO	Complete if Known		
		Application Number	10/802,273	
INFORM	ATION DISCLOSURE	Filing Date	03/17/04	
INFORMATION DISCLOSURE		First Named Inventor	Rodriguez	
	ENT BY APPLICANT	Art Unit	1614	
(Use a	is many sheets as necessary)	Examiner Name	Leslie A. Royds	
Sheet 2	of 18	Attorney Docket Number	31162B	

<del></del>			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WAR		US- 5,314,694	05-24-1994	Gale et al.	
LAN		<sup>US-</sup> 5,382,573	01-17-1995	Casper	
NER		<sup>US-</sup> 5,416,091	05-16-1995	King	
VAR		<sup>US-</sup> 5,418,228	05-23-1995	Bennink	
HAL		<sup>US-</sup> 5,422,119	06-06-1995	Casper	
NAR		<sup>US-</sup> 5,461,041	10-24-1995	Bergink et al.	
WAL		US- 5,468,736	11-21-1995	Hodgen	
WL		US- 5,552,394	09-03-1996	Hodgen	
LOO		<sup>US-</sup> 5,583,129	12-10-1996	Spona et al.	
UPOL		<sup>US-</sup> 5,595,970	01-21-1997	Garfield et al.	
HAR		<sup>US-</sup> 5,620,705	04-15-1997	Dong et al.	
We		<sup>US-</sup> 5,633,011	05-27-1997	Dong et al.	
NA		<sup>US-</sup> 5,747,480	05-05-1998	Gast	
AL		<sup>US-</sup> 5,780,497	07-14-1998	Miller et al.	
LAR		US- 5,842,476	12-01-1998	Wright et al.	
UAR		<sup>US-</sup> 5,855,906	01-05-1999	McClay	
IAR		<sup>US-</sup> 5,858,405	01-12-1999	Gast	
NA		<sup>US-</sup> 5,888,543	03-30-1999	Gast	
NAR		<sup>US-</sup> 5,891,868	04-06-1999	Cummings et al.	

Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	Γ
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>3</sup> (# known)	MM-DD-YYYY		Or Relevant Figures Appear	Τ,
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Substitute for form 1449/PTO	Complete if Known		
	Application Number	10/802,273	
INFORMATION DISCLOSURE	Filing Date	03/17/04	
	First Named Inventor	Rodriguez	
STATEMENT BY APPLICANT	Art Unit	1614	
(Use as many sheets as necessary)	Examiner Name	Leslie A. Royds	
neet 3 of 8	Attorney Docket Number	31162B	

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.¹	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
NAM		<sup>US-</sup> 5,898,038	04-27-1999	Yallampalli et al.	
LAR		<sup>US-</sup> 5,922,349	07-13-1999	Elliesen et al.	
LAR		<sup>US-</sup> 6,028,064	02-22-2000	Rodguez et al.	
hore		US- 6,034,074	03-07-2000	Rodguez et al.	
HAR		<sup>US-</sup> 6,310,054	10-30-2001	Rodguez et al.	
MAR		<sup>US-</sup> 6,319,911	11-20-2001	Rodguez et al.	
LIGH		us- 6,407,082	06-18-2002	Rodguez et al.	
NAL		US- 6,444,658	09-03-2002	Rodguez et al.	
LAGE		<sup>US-</sup> 6,511,970	01-28-2003	Rodguez et al.	
hPd		<sup>US-</sup> 6,765,002	07-20-2004	Rodguez et al.	
LAR		<sup>US-</sup> 6,977,250	12-20-2005	Rodguez et al.	
LAR		<sup>US-</sup> 7,053,074	05-30-06	Rodguez et al.	
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		FOREIGI	N PATENT DOCU	MENTS		
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stitute for form 1449/PTO		Complete if Known	•
	Application Number	10/802,273	•
FORMATION DISCLOSURE	Filing Date	03/17/04	_

STATEMENT BY APPLICANT **First Named Inventor** Rodriguez Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Leslie A. Royds Attorney Docket Number Sheet 18 31162B of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
iar		ARCHER, et al., A new low-dose monophasic combination oral contractive (Alesse) with levonorgestrel 100 mg and Ethinyl Estradiol 20 mg, Contraception, (1997) 55:139-144	
NAC	-	BAST, et al., Ovarian Cancer, Harrison's Principles of Internal Medicine, 1994, Chapter 321, 13th Ed., Isselbacher et al., (Eds.) pp. 1853-1858, McGraw-Hill, New York	
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LAGOL		CASAGRANDE, et al., "Incessant Ovulation" and Ovarian Cancer, The Lancet, July 28, 1979, pp. 170-172, Los Angeles, California	
Me		EVANGELOU, et al., Down-regulation of Transforming Growth Factor B receptors by androgen in ovarian cancer cells, Cancer Research, 2000, 60:929-935	
LAL		FRANSESCHI, et al., Pooled Analysis of 3 European Case-Control Studies of Epithelial Ovarian Cancer: III. Oral Contraceptive Use, Int. J. Cancer, 1991, 49:61-65, Wiley-Liss	
WAR		GREENE, et al., The Epidemiology of Ovarian Cancer, Seminars in Oncology, September 1984, pp. 209-225, Vol. 11, No. 3, USA	
UAR		GRIMES, et al., Primary Prevention of Gynecologic Cancers, Am. J. Obstet. Gynecol., January 1995, pp. 227-235, San Francisco, California	
LAR		GROSS, et al., The Estimated Effect of Oral Contraceptive Use on the Cumulative Risk of Epithelial Ovarian Cancer, OCs and Ovarian Cancer, 1994 pp. 419-424, Vol. 83, No. 3 USA	
WAL	۱۸	HAMMOND, Climacteric, Danforth's Obstetrics and Gynecology, 1994, pp. 771-790, Chapter 42, 7th Ed., Philadelphia	

Examiner Signature	Date Considered	11000BER 2006

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Initial coopie coby of this form with pext communication to applicant.

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	Application Number	10/802,273	
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03/17/04 STATEMENT BY APPLICANT **First Named Inventor** Rodriguez Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Leslie A. Royds Sheet Attorney Docket Number 31162B 8

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
UAL		HICKEY, et al., Metabolic and Endocrinologic Effects of Steroidal Contaception, J. Sciarra Editor, 1996, pp. 1-14, Vol. 6, Chapter 24, Lippincott, Philadelphia	
LAR		JORDAN, The Estrogenic Activity of Synthetic Progestins Used in Oral Contraceptives, Cancer, 1993, Vol. 71, No. 4, pp. 1501-1505	
MAR		LEE, The Reduction in Risk of Ovarian Cancer Associated with Oral Contraceptive Use, 1987, New Engl. J. Med., 316:650-655	
LASE		LEFKOWITZ, et al., Sunlight, Vitamin D, and Ovarian Cancer Mortality Rates in US Women, International Journal of Epidemiology, 1994, pp. 1133-1136, Vol 23, No 6, Great Britian	
LARL		LIANG, et al., Risk of Breast, Uterine Corpus, and Ovarian Cancer in Women Receiving Medroxyprogesterone Injections, JAMA, 1983, pp. 2909-2912, Vol. 249, No. 21, USA	
WAR		LINGEMAN, Etiology of Cancer of the Human Ovary: A Review, The Journal of the National Cancer Institute, December 1974, pp. 1603-1618, Vol. 53, No. 6	
WAR		LOCKER, et al. Hormonal Therapy of breast cancer, Cancer Treatment Reviews, 1998, Vol. 24, pp. 221-240, W.B. Saunders Company Ltd.	
WAYL		LOCKSHIN, et al., The Biology of Cell Death and Its Relationship to Aging, Cellular Aging and Cell Death, 1996, pp. 167-180, Wiley-Liss Inc.	
WAR		LOWE, et al., p53-Dependent Apoptosis in Tumor Progression and in Cancer Therapy, Cellular Aging and Cell Death, 1996, pp. 209-234, Wiley-Liss, Inc.	
LAYL		LUNDGREN, et al., Progestins in Breast Cancer treatment, ACTA Oncolgica, 1992, Vol. 31, No. 7, pp. 709-722, Trondheim, Norway.	

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<sup>&</sup>quot;EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ubstitute for form 1449/PTO		Complete if Known
	Application Number	10/802,273
NFORMATION DISCLOSURE	Filing Date	03/17/04
STATEMENT BY APPLICANT	First Named Inventor	Rodriguez
(Use as many sheets as necessary)	Art Unit	1614
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Attorney Docket Number

31162B

Sheet 6

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
in		MAGOFFIN, et al.,, Estradoil-17B, insulin like growth factor-1, and lutienizing hormone inhibit secretion of transforming growth factor B by rat ovarian theca-interstitial	
V		(continued from above) cells, Biology of Reproduction, 1995, 53, pp. 627-635	
WAR		MUSS, et al., High-dose progestin therapy for metastic breast cancer, Annals of Oncology, 1992, pp. S15-S20, Vol. 3, Netherlands	
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		(continued from above) Oncology Associate Study, Journal of Clinical Oncology, 1994, pp. 1630-1638, Vol. 12, No. 8	
LAL		MUTCH, et al., Biology of Epithelial Ovarian Cancer, Clinical Obstetrics and Gynecology, 1994, pp. 406-422, Vol. 37, No. 2, L.B. Lippincott Co.	
UAR		PFLEIDERER, The Problems of Prophylactic Chemotherapy, Second-look Surgery, and Maintenance of Remission in Therapy of Ovarian Cancer, Geburtshilfe und Frauenheiklunde,	
V		(continued from above) 1976, pp. 132-139, Vol. 36, Germany	
MY		RAVIN, et al., Preformulation, Remington's Pharmaceutical Sciences, 1990, pp. 1435-1712, Chapters 75-92, Mack Publishing Co., Easton, PA	
UANL	Λ	RODRIGUEZ, et al., Estrogen Replacement Therapy and Fatal Ovarian Cancer, American Journal of Epidemiology, 1995, pp. 828-835, Vol. 141, No. 9, USA	

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STATEMENT BY APPLICANT				First Named Inventor	Rodriguez		
	(Use as many she	ante se n	acassary)	Art Unit	1614		
(200 20 11011) 211020 20 11002021,				Examiner Name	Leslie A. Royds		
Sheet	7	of	8	Attorney Docket Number	31162B		

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
LAL		ROSENBERG, et al., A Case-Control Study of Oral Contraceptive Use and Invasive Epithelial Ovarian Cancer, 1994, pp. 654-661, Vol. 139, No. 7, USA	
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Examiner Signature	MULLIK	/ WOM?	$\mathcal{V}$	Date Considered	11 atober 2006

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INF	ORMATION	DIS	CLOSURE	Filing Date	03/17/04	•:
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		NON PATENT LITERATURE DOCUMENTS	
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JML.		VOGEL, Update on the current use of hormonals as therapy in advanced breast cancer, use of homonals in advanced breast cancer, Anti-Cancer Drugs, 2003, 14:265-273	
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Examiner	VAUTOR	AHAMA	Date	
Signature	MILLER	XXXXXX	Considered     W	00106942000

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